

**In the claims**

Please cancel claims 1-4 and 9-10 without prejudice and acquiescence.

**REMARKS/ARGUMENTS**

Applicants have amended the paragraph on page 5, lines 14-32 to recite the date of the deposit and the address of ATCC. Applicants assert that the biological material was deposited with the ATCC under the terms of the Budapest Treaty. A marked up version of the paragraph with the amendment is attached to this response as Appendix A.

Claims 5-8 and 11-12 are pending in this application. Claims 1-4 and 9-10 have been canceled without prejudice and acquiescence as they are drawn to a non-elected invention. Applicant maintains the right to pursue these claims in a divisional application. For the convenience of the Examiner, Applicant has attached as Appendix B a clean copy of the pending claims. No new matter has been added.

The issues outstanding in this application are as follows:

- The specification has been rejected under 35 U.S.C. §112(1), which the Office Action alleges the specification does not provide adequate disclosure of the claims.
- A defective Oath.
- Claims 5 and 11 have been rejected under 35 U.S.C. §102(b), which the Office Action alleges that the claimed subject matter is anticipated by Dran et al.

Applicant respectfully traverses the outstanding rejections and objections, and applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

A. Oath is Acceptable.

The Action noted that a new oath needed to be submitted because the filed oath did not indicate the citizenship of the inventors. Applicants hereby submit a newly executed oath which clearly indicates the citizenship of the inventors.

B. The Specification meets all requirements.

The Action has rejected the specification under 35 U.S.C. §112(1) because the specification allegedly does not contain complete evidence that the biological materials are known or deposited. Applicants traverse.

Applicants are confused as to why the specification was rejected. The specification can be "objected" to for the above reasons, however, Applicants do not believe that the specification can be rejected. Thus, Applicants believe that the rejection is improper and request it be withdrawn.

However, in order to advance the prosecution of the present application, Applicants have amended the specification to recite the name and address of the depository and the dates of the deposit. Yet further, Applicants also enclose herewith notification from ATCC indicating the deposition of the biological material. In light of this amendment, Applicant respectfully requests withdrawal of the rejection.

C. Claims 5 and 11 are not anticipated.

Claims 5 and 11 have been rejected under U.S.C. § 102(b), which the Office Action alleges that the claimed subject matter is anticipated by Duran et al. Applicants respectfully traverse.

Anticipation under section 102 requires that a single prior art reference disclose the same invention, including each element and limitation of the claims in issue. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Indeed, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Id.*

Applicants assert that Dran et al does not anticipate the present invention. Dran et al

is drawn to methods of using primary cell culture. Primary cell culture involves the use of cells that have been isolated from tissues. Primary cell cultures are only capable of propagating for a limited number of divisions. At some point, the cells cease dividing and proceed through cell senescence. This is opposite of cell lines. Cell lines are capable of dividing indefinitely in culture (Molecular Biology of the Cell, page 892, 1994). Cell lines are immortalized cells. Thus, these cells do not senesce. Yet further, cell line cultures are homogeneous. Primary cultures are inherently heterogeneous.

Cell lines are derived from tissue, similar to primary culture, however during culture, some of the cells escape senescence and divide indefinitely. The cells that escape senescence are used to develop the immortalized cell line. Once the cell line is developed, isolation of cells from tissue is not needed. This is opposite of primary culture. In primary culture, the cells are mortal. Once the cells begin senescence, the culture is not viable. At this point, cells must be re-isolated from tissue.

Applicants clearly have developed a cell line, not a primary culture as in Dran et al. For example, on pages 24-25 in the Specification, Applicants isolate cells from a tumor. These cells are grown in culture. After time, the cells started to grow with a completely different pattern than that of the parental cells. This morphological change from the parental cell is an indication of a cell line. It is known by those of skill in the art that cell lines have a slightly different morphology than the primary cultures. The immortality of cell lines reflects one or more alterations in the cell that results in their proliferative properties. In the specification on page 13, lines 7-20, Applicants describe the morphological aspects of the developed cell lines.

In light of this, Applicant asserts that there is a clear difference between the present invention and the Dran reference. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of claims 5 and 11.

### CONCLUSION

Claims 5-8 and 11-12 are pending in this application. Applicant believes that there are no fees associated with the filing of this document. However, the Commissioner is hereby authorized to any required fees associated with this filing, to Deposit Account No. 06-2375, under Order No. 10018082, from which the undersigned is authorized to draw.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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Respectfully submitted,

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## Appendix A

### Version Showing Changes Made

The present invention also relates a mouse mammary adenocarcinoma cell line MC7-L1 which is derived from the murine progestin-independent C7-HI tumor, wherein the cell line expresses ER and PR and is deposited with the have been deposited on October 28, 1999 with American Type Culture Collection (ATCC), 1081 University Blvd, Manassas, Virginia 20110-2209 ~~ATCC~~ as Accession number PTA-890.

## Appendix B

### Claims pending as of March 5, 2002

5. A non transgenic mouse mammary adenocarcinoma cell line derived from a murine progestin-independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors.

6. The non transgenic mouse mammary adenocarcinoma cell line of claim 5, wherein the cell line is MC7-L1.

7. A non-transgenic mouse mammary adenocarcinoma cell line system for testing the activity of a hormone, an anti-hormone, a pharmacological compound and an environmental agent, wherein the system comprises a MC7-L1 cell line.

8. An *in vitro* method for testing the activity of a hormone, an anti-hormone, a pharmacological compound or an environmental agent, comprising the steps of:

cultivating a cell line system, wherein the cell line system comprises

a MC7-L1 cell line derived from a murine progestin-independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors;

exposing the cell line system to the hormone, the anti-hormone, the pharmacological compound, or the environmental agent; and

quantifying cell proliferation.

11. A kit for determining the effect of a hormone, anti-hormone, pharmacological compounds and environmental agents, wherein the kit comprises an aliquot, a cell line, and a method for evaluating the proliferation of cells.

12. The kit of claim 11, wherein the cell line is MC7-L1.